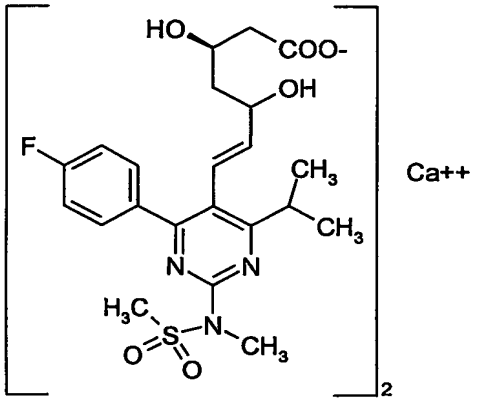
We claim:

1. Amorphous rosuvastatin calcium of Formula I having a purity of more than 99% with diastereomeric impurity less than 0.5% by HPLC.



FORMULA I

2. The amorphous form of rosuvastatin calcium of claim 1, wherein the rosuvastatin calcium has the X-ray diffraction pattern of Figure 1.

3. A pharmaceutical composition comprising:

a therapeutically effective amount of an amorphous form of rosuvastatin calcium having purity greater than 99% with diastereomeric impurity less than 0.5% by HPLC; and one or more pharmaceutically acceptable carriers, excipients or diluents.

4. The pharmaceutical composition of claim 1, wherein the rosuvastatin calcium has the X-ray diffraction pattern of Figure 1.

5. Amorphous rosuvastatin calcium having a purity of more than 99.5% with diastereomeric impurity less than 0.25% by HPLC.

6. Amorphous rosuvastatin calcium having a purity of more than 99.8% with diastereomeric impurity less than 0.15% by HPLC.

7. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

obtaining a solution of rosuvastatin calcium in one or more solvents; and recovering the rosuvastatin calcium in the amorphous form from the solution thereof by the removal of the solvent.

8. The process of claim 7, wherein the solvent comprises one or more of lower alkanol, ketone, ether, ester, polar aprotic solvent, water, or mixtures thereof.

9. The process of claim 8, wherein the lower alkanol comprises one or more of primary, secondary and tertiary alcohol having from one to six carbon atoms.

10. The process of claim 8, wherein the lower alkanol comprises one or more of methanol, ethanol, n-propanol, and isopropanol.

11. The process of claim 8, wherein the ketone comprises one or more of acetone, ethyl methyl ketone, methyl isobutyl ketone, and diisobutyl ketone.

12. The process of claim 8, wherein the ether comprises one or both of tetrahydrofuran, and 1,4-dioxane.

13. The process of claim 8, wherein the ester comprises one or more of ethyl formate, methyl acetate, ethyl acetate, isopropyl acetate, n-propyl acetate, isobutyl acetate, butyl acetate, and amyl acetate.

14. The process of claim 8, wherein the polar aprotic solvent comprises one or more of N,N-dimethylformamide, N,N-dimethylacetamide, dimethylsulphoxide, acetonitrile, and N-methylpyrrolidone.

15. The process of claim 7, wherein removing the solvent comprises one or more of distillation, distillation under vacuum, evaporation, spray drying, freeze-drying, lyophilization, filtration, filtration under vacuum, decantation, and centrifugation.

16. The process of claim 15 further comprising adding additional/second solvent before removing the solvent.

17. The process of claim 16, wherein the additional/second solvent comprises one or more of isopropanol, isobutanol, n-butanol, cyclopentane, cyclohexane, cycloheptane, hexane, petroleum ether, heptane, diethyl ether, diisopropyl ether, water, or mixtures thereof.

18. The process of claim 7, wherein the rosuvastatin calcium in an amorphous form is recovered from the solution by distillation.

19. The process of claim 18, wherein the distillation is carried out under vacuum.

20. The process of claim 7, wherein the rosuvastatin calcium in an amorphous form is recovered from the solution by spray drying.

21. The process of claim 7, wherein the rosuvastatin calcium in an amorphous form is recovered from the solution by filtration.

22. The process of claim 7, further comprising additional drying of the product obtained.

23. The process of claim 7, further comprising forming the product obtained into a finished dosage form.

24. The process of claim 7, wherein the rosuvastatin calcium has the X-ray diffraction pattern of Figure 1.

25. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

subjecting crystalline rosuvastatin calcium to milling until said crystalline form is converted to the amorphous form.

26. The process of claim 25, wherein the crystalline form used is in solid state.

27. The process of claim 25, wherein slurry of the crystalline form in a solvent is used.

28. The process of claim 27, wherein the solvent comprises one or more of isopropanol, isobutanol, n-butanol, cyclopentane, cyclohexane, cycloheptane,

hexane, petroleum ether, heptane, diethyl ether, diisopropyl ether, or mixtures thereof.

29. The process of claim 25, further comprising additional drying of the product obtained.

30. The process of claim 25, further comprising forming the product obtained into a finished dosage form.

31. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

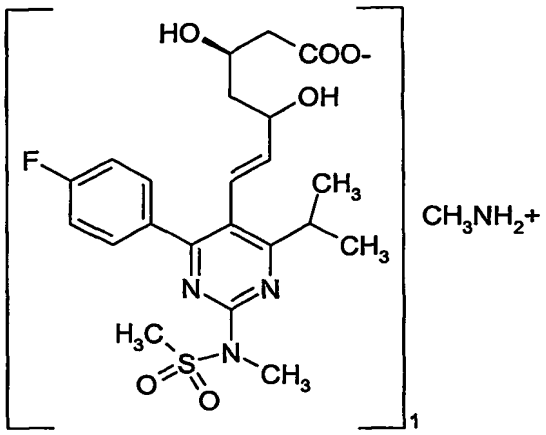
obtaining a solution of rosuvastatin calcium in one or more solvents; and recovering the rosuvastatin calcium in the amorphous form from the solution thereof by freeze drying or lyophilizing.

32. The process of claim 31, wherein the solvent comprises one or more of lower alkanol, ketone, ether, ester, polar aprotic solvent, water, or mixtures thereof.

33. The process of claim 32, wherein the solvent comprises one or more of methanol, ethanol, isopropanol, n-propanol, tetrahydrofuran, 1,4-dioxane, ethyl formate, methyl acetate, ethyl acetate, isopropyl acetate, n-propyl acetate, isobutyl acetate, butyl acetate, amyl acetate, acetone, ethyl methyl ketone, methyl isobutyl ketone, diisobutyl ketone, N,N-dimethylformamide, N,N-dimethylacetamide, dimethylsulphoxide, acetonitrile, and N-methylpyrrolidone.

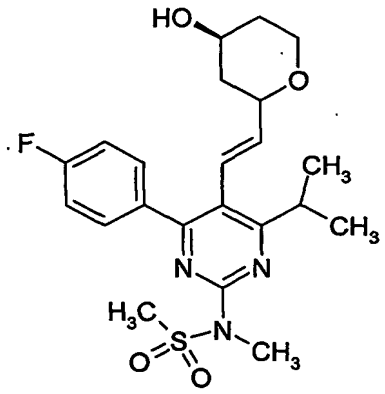
34. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

a) lactonizing rosuvastatin methyl ammonium salt of Formula II,



FORMULA II

to obtain rosuvastatin lactone of Formula III,



FORMULA III

b) reacting the rosuvastatin lactone with a base and a calcium salt, and

c) recovering the amorphous form of rosuvastatin calcium.

35. The process of claim 34, wherein the lactonization is carried out in the presence of an acid in a solvent.

36. The process of claim 35, wherein the acid comprises one or both of inorganic acid and organic acid.

37. The process of claim 35, wherein the acid comprises one or more of hydrochloric acid, sulfuric acid, nitric acid, phosphoric acid, formic acid, acetic acid, or mixtures thereof.

38. The process of claim 35, wherein the solvent comprises one or more of toluene, xylene, benzene, ethyl methyl ketone, diisobutyl ketone, methyl isobutyl ketone, methyl t-butyl ether, diisopropyl ether, ethyl acetate, methyl formate, methyl acetate, isobutyl acetate, n-propyl acetate, isopropyl acetate, amyl acetate, or mixtures thereof.

39. The process of claim 34, wherein the rosuvastatin lactone is isolated.

40. The process of claim 34, wherein the base comprises one or more of sodium hydroxide, sodium carbonate, sodium bicarbonate, potassium hydroxide, potassium carbonate, and potassium bicarbonate.

41. The process of claim 34, wherein the calcium salt comprises one or more of calcium chloride, calcium hydroxide, calcium carbonate, calcium acetate, calcium sulphate, calcium borate, calcium tartarate, and calcium bromide.

42. The process of claim 34, further comprising additional drying of the product obtained.

43. The process of claim 34, further comprising forming the product obtained into a finished dosage form.

44. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

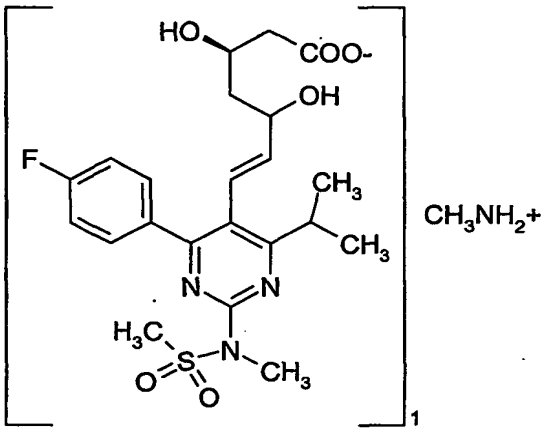
treating rosuvastatin methyl ammonium salt with a base and a calcium salt; and recovering the amorphous form of rosuvastatin calcium.

45. The process of claim 44, wherein the base comprises one or more of sodium hydroxide, sodium carbonate, sodium bicarbonate, potassium hydroxide, potassium carbonate, and potassium bicarbonate.

46. The process of claim 44, wherein the calcium salt comprises one or more of calcium chloride, calcium hydroxide, calcium carbonate, calcium acetate, calcium sulphate, calcium borate, calcium tartarate, and calcium bromide.

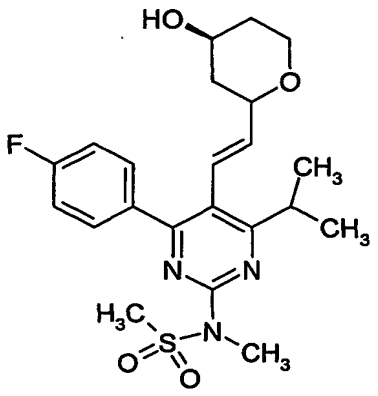
47. A process for the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

a) lactonizing rosuvastatin methyl ammonium salt of Formula II,



FORMULA II

to obtain rosuvastatin lactone of Formula III,



FORMULA III

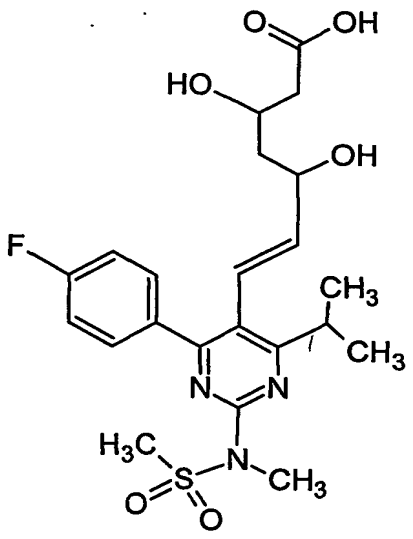
b) reacting the lactone form of rosuvastatin with a base and a calcium salt,

c) removing water from reaction mass by azeotropic distillation to obtain a solution containing rosuvastatin calcium, and

d) recovering the amorphous form of rosuvastatin calcium by removing solvent from the resultant solution.

48. A process of the preparation of pure amorphous form of rosuvastatin calcium, the process comprising:

a) treating rosuvastatin calcium with an acid to obtain rosuvastatin of Formula IV, and



FORMULA IV

b) converting the rosuvastatin to the amorphous form of rosuvastatin calcium by treatment with a base and a calcium salt.

49. The process of claim 48, wherein the acid comprises one or both of inorganic acid and organic acid.

50. The process of claim 48, wherein the acid comprises one or more of hydrochloric acid, sulphuric acid, phosphoric acid, hydrobromic acid, nitric acid, formic acid, acetic acid, propionic acid, methanesulphonic acid, 4-toluenesulphonic acid, or mixtures thereof.

51. The process of claim 48, wherein the calcium salt comprises one or more of calcium chloride, calcium hydroxide, calcium carbonate, calcium acetate, calcium sulphate, calcium borate, calcium tartarate, and calcium bromide.

52. The process of claim 48, wherein the rosuvastatin is isolated.

53. The process of claim 48, further comprising forming the product obtained into a finished dosage form.

54. A method of treating hyperlipidemia, hypercholesterolemia, and atherosclerosis in a warm-blooded animal comprising administering a pharmaceutical composition that includes the pure amorphous form of rosuvastatin calcium having a purity of more than 99% with diastereomeric impurity less than 0.5% by HPLC.